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Name: Mail Stop AMENDMENT
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Subject: U.S. Patent Application No. 08/480,908
Gary K. Michelson
Filed: June 7, 1995
THREADED FRUSTO-CONICAL INTERBODY SPINAL FUSION IMPLANTS
Attorney Docket No. 101.0053-00000
Customer No. 22882

FROM:

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Phone No.: 330-877-2277

No. of Pages (including this): 35

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I hereby certify that the attached Transmittal Form (in duplicate; $1,020.00 total amount to cover the three-month extension fee is to be charged to Deposit Account No. 50-1068), Reply to Office Action, Declaration of Gary K. Michelson Under 37 C.F.R. § 1.131 with Exhibits A and B, and Declaration of Amedeo F. Ferraro with Exhibits A-H are being facsimile transmitted to the U.S. Patent and Trademark Office on September 30, 2005.

Todd M. Martin

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or other fusion enhancing material. Some examples of such materials are bone harvested from the patient, or bone growth inducing material such as, but not limited to, hydroxyapatite, hydroxyapatite tricalcium phosphate; or bone morphogenic protein. The cap 148 and/or the spinal fusion implant 120 may be made of but not limited to any material appropriate for human implantation including metals such as cobalt chrome, stainless steel, titanium, plastics, ceramics, composites and/or may be made of, and/or filled, and/or coated with a bone ingrowth inducing material such as, but not limited to, hydroxyapatite or hydroxyapatite tricalcium phosphate or any other osteoconductive, osteoinductive, osteogenic, or other fusion enhancing material. The cap 148 and the implant 120 may be partially or wholly bioabsorbable.

Referring to Figure 4, an alternative embodiment of the spinal fusion implant of the present invention is shown and generally referred to by the numeral 220. The implant 220 has a frusto-conical body 222 and has a surface configuration of forward facing ratchetings 240 suitable for engaging the bone of the adjacent vertebrae. Each of the plurality of ratchetings 240 has a bone engaging edge 242 and ramped portion 244.

The orientation of the ratchetings 240 makes the insertion of the implant 220 easier than its removal, as the ramped portions 244 act as an inclined plane on the way in, while the bone engaging edges 242 resist motion in the opposite directions. These forward facing ratchetings 240 tend to urge the implant 220 forward until the unremoved bone of the vertebrae blocks further motion resulting in a very stable spine and implant construct.

In the preferred embodiment, the bone engaging edges 242 of the ratchetings 240 have a height at a highest point measured from the root diameter of the implant 220 in the range of 0.25 - 2.0 mm, with the preferred height being 0.4 mm for use in the cervical spine and 1.25 mm for use in the lumbar spine.

Referring to Figures 5 and 6, cross sectional views of implant 220 are shown. The implant 220 has channels 250 passing through the implant 220 and wells 260 formed in the surface of the implant 220. The wells 260 may or may not communicate with the

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channels 250. In the preferred embodiment of implant 220, the channels 250 have a diameter in the range of 0.1 mm to 6 mm, with 2-3 mm being the preferred diameter. The wells 260 have a diameter in the range of 0.1 mm to 6 mm, with 1-3 mm being the preferred diameter range. It is appreciated that although the channels 250 and wells 260 are shown having a generally rounded configuration, it is within the scope of the present invention that the channels 250 and wells 260 may have any size, shape, configuration, and distribution suitable for the intended purpose.

Referring to Figures 4A and 4B, an alternative embodiment of the implant 220 is shown and generally referred to by the numeral 220'. The implant 220' has ratchetings 240' having a radius R_4 measured from the longitudinal central axis L_4 that increases in size from the insertion end 224' to the trailing end to the trailing end 226'. The ratchetings 240' each have a height measured from the body 222' that is not constant throughout the length of the implant 220'. In the preferred embodiment, the thread radius R_4 and the trhead height increase in size from the insertion end 224' to the trailing end 226'.

As shown in Figure 4B, the implant 220' has truncated sides 270 and 272 forming two planar surfaces which are diametrically opposite and are parallel to the longitudinal axis L_4. In this manner, two implants 220' may be placed side by side with one of the sides 270 or 272 of each implant touching, such that the area of contact with the bone of the adjacent vertebrae and the ratchetings 240' is maximized.

Referring to Figures 7-9A, an alternative embodiment of the spinal fusion implant of the present invention is shown and generally referred to by the numeral 320a. The implant 320a is shown placed next to a second implant 320b shown in hidden line. The implant 320a has a body 322 that is made out of a mesh-like material comprising strands which may be made of metal that are pressed together and molded into a partially frusto-conical configuration. The implant 320a has an insertion end 324 and a trailing end 326 and may be made entirely of a mesh-like material or may comprise an outer covering made of the mesh-like material.

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It is appreciated that the implant 320a may be solid or may be partially hollow and include at least one internal chamber.

As shown in Figure 9A, the mesh-like material comprises strands that are formed and pressed together such that interstices 339, capable of retaining fusion promoting material and for allowing for bone ingrowth, are present between the strands in at least the outer surface 338 of implant 320.

Referring to Figure 9B, alternatively the implant 320a may be made of a cancellous material 350 such that the outer surface 338 has a configuration as shown in Figure 9B. As the implant 320a may be made entirely or in part of the cancellous material 350, the interstices 352 may be present in the outer surface 338 and/or within the entire implant 320a to promote bone ingrowth and hold bone fusion promoting materials.

Referring again to Figure 8, the implant 320a is partially frusto-conical, similar to implant 20, and having at least one truncated side 340 that forms a planar surface parallel to the longitudinal axis of implant 320. The truncated side 340 allows for the placement of two implants 320a and 320b closer together when placed side by side between two adjacent vertebrae as set forth in U.S. Patent Application Serial No. 08/390,131, incorporated herein by reference implant 320a may be partially threaded or may otherwise resemble any of the other embodiments herein described or that are functionally equivalent.

Referring to Figure 10, a side elevational view in partial cut-away of an alternative embodiment of the implant of the present invention is shown and generally referred to by the numeral 420. The implant 420 has a body 422 that is frusto-conical in shape having an insertion end 424 and a trailing end 426. The implant 420 has an outer surface 438 that is capable of receiving and holding bone, or other materials capable of participating in the fusion process and/or capable of promoting bone ingrowth. In the preferred embodiment, the surface 438 comprises a plurality of posts 440 that are spaced apart to provide a plurality of interstices 442 which are partial wells with incomplete walls capable of holding and retaining milled bone material or any

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artificial bone ingrowth promoting material. The implant 420 may be prepared for implantation by grouting or otherwise coating the surface 438 with the appropriate fusion promoting substances.

Referring to Figure 11, an enlarged view of the surface 438 of implant 420 is shown. In the preferred embodiment, the posts 440 have a head portion 444 of a larger diameter than the remainder of the posts 440, and the each of the interstices 442 is the reverse configuration of the posts 444 having a bottom 446 that is wider than the entrance 448 to the interstices 442. Such a configuration of the posts 440 and interstices 442 aids in the retention of bone material in the surface 438 of the implant 420 and further assists in the locking of the implant 420 into the bone fusion mass created from the bone ingrowth, while providing for an improvement in the available amount of surface area which may be still further increased by rough finishing, flocking or otherwise producing a non smooth surface.

In the preferred embodiment, the posts 440 have a maximum diameter in the range of approximately 0.1-2 mm and a height of approximately 0.1-2 mm and are spaced apart a distance of approximately 0.1-2 mm such that the interstices 442 have a width in the range of approximately 0.1 to 2mm. The post sizes, shapes, and distributions may be varied within the same implant.

The embodiments of the frusto-conical implants of the present invention described above may be implanted with the method described below.

In the preferred method of the present invention, the diseased disc between two vertebrae is at least partially removed. The two vertebrae adjacent the diseased disc are then optimally distracted and placed in the desired amount of lordosis by any of a number of well known means including, but not limited to, those means that distract the vertebral bodies by engaging screws placed into the anterior aspect of the vertebral bodies, and disc space distractors that are placed from the anterior aspect of the spine into the disc space and are then used to urge the vertebral endplates away from each other and into lordosis. When the correct amount of distraction and lordosis have been achieved at the

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affected disc level, then a frusto-conical space is created from anterior to posterior between the adjacent vertebrae. The frusto-conical space that is created is greater in diameter than the disc space height, such that some bone is removed from each of the adjacent vertebrae. The created space is generally frusto-conical in shape, being greatest in diameter anteriorly and tapering to a lesser diameter posteriorly.

It should be noted that where the spine is of sufficient width, it may be possible to prepare two such frusto-conical spaces side-by-side at the same disc level, allowing for the use of two implants instead of one. In either event, once the frusto-conical space is prepared and all debris removed, the implant is then inserted into the prepared space across the disc space, penetrating into each of the adjacent vertebrae, from anterior to posterior.

In the preferred embodiment, the diseased disc is first removed by conventional discectomy. The depth of the disc space is then determined by direct measurement. An interspace distractor such as that described by Michelson in U.S. Patent Application Serial No. 08/396,414 entitled apparatus and method of inserting spinal implants, incorporated herein by reference, is then inserted into the disc space. A series of such distractors are available and are sequentially inserted until the optimal amount of distraction across the disc space is achieved. The interspace distractors utilized for this purpose are wedged so as to induce physiological lordosis. An outer sleeve is then fitted over the barrel portion of the interspace distractor and firmly seated in engagement with the spine. As previously described in U.S. Patent Application Serial No. 08/396,414, said outer sleeve may itself have extended portions capable of either maintaining or of obtaining and maintaining distraction. Said outer sleeve may also have vertebrae engaging prongs to further stabilize the outer sleeve to the spine and to more rigidly control motion at the adjacent vertebrae. As described in U.S. Patent Application Serial No. 08/396,414, the use of the extended outer sleeve with distractor portions actually makes it possible to achieve the optimal distraction and lordosis without the use of the described

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interspace distractor. However, if the interspace distractor is used, then the outer sleeve is fully engaged to the spine, the distractor is removed, and in the preferred method by use of a slap-hammer, engaging the most proximal aspect of the distractor.

Referring to Figure 12, a segment of the spinal column S is shown with vertebrae V_1 and V_2 shown in lordosis adjacent to disc space D_1 and vertebrae V_2 and V_3 shown not in lordosis but relatively paralell to each other adjacent disc space D_2. A first drill 510 having an opening 512 across the disc space D_1, and into adjacent vertebrae V_1 and V_2, and a second drill 520 having an opening 522 across the disc space D_2 and into adjacent vertebrae V_2 and V_3 are shown in Figure 12. In the preferred embodiment, the interbody spinal fusion implant itself is threaded and frusto-conical in shape and therefore, the remaining portion of the procedure will be described in regard to that particular embodiment of the present invention. With the disc space fully distracted and in anatomical lordosis and with the outer sleeve firmly engaged to the spine, it is then desirable to prepare the spine for receipt of the interbody fusion implant. It is preferable to prepare a space across the disc space and penetrating into the adjacent vertebrae which space corresponds roughly to the root dimensions of the implant to be implanted. For this purpose, a stopped-out bone cutting instrument is inserted through the outer sleeve, the shape of the cutting portion of the first drill 510 generally corresponding to the frusto-conical shape of the root diameter of the implant being inserted. This instrument may take the form of a frusto-conical drill or a mill and may be used to cut the bone by rotation, said rotation being achieved either through a manual handle or with power. Having prepared the space, the surgeon has two options. One is to remove the outer sleeve and then, because the implant is itself frusto-conical, screw the implant in using an implant driver capable of locking to the implant. The other is to leave the outer sleeve in place during the insertion of the implant.

If the surgeon wishes to remove the outer sleeve, the insertion of the implant itself causes a reproduction of the

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previous distraction which is easily achieved as the implant itself is frusto-conical in shape and the space created by the removal of the bone to either side of the disc space essentially corresponds to the root diameter of the implant such that as the implant is inserted, the threads are embedded into the vertebrae adjacent the disc space. Once the implant is fully inserted, the insertion apparatus is disconnected from the implant. If the cervical disc space is sufficiently wide from side-to-side, the procedure is performed in the same manner except that either a double-barrelled outer sleeve may be used or the previously described procedure essentially performed twice at the same disc level, such that a pair of implants may be inserted side-by-side.

In the alternative, if the surgeon wishes to leave the outer sleeve in place during the insertion of the implant and if the implant, as per this example has both a minor and a major diameter such as with a threaded implant, then the bone removing portion of the drilling means needs to generally correspond to the root diameter of the implant while the inside diameter of the outer sleeve needs to be great enough to allow the passage of the major diameter of the implant. As it is desirable to stabilize the bone removal instrument and to assure that it removes equal portions of bone from each of the adjacent vertebrae. This may be achieved by a reduction sleeve which fits between the bone removal means and the inner wall of the outer sleeve and which essentially corresponds to the difference between the minor and major diameters of the implant, or some portion of the drill shaft proximal to the cutting end may have a diameter which corresponds to the major diameter of the implant even while the distal bone removing portion corresponds to the root diameter of the implant. In either way, the bone removal instrument is both stabilized and centered within the outer sleeve.

The approach to the lumbar spine may either be retroperitoneal, or transperitoneal. The procedure may be performed under direct vision, or laproscopically with the use of an endoscope. Generally it is preferable to utilize two implants which are inserted in an anterior to posterior direction, one to

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either side of the midline. The implants may be inserted using either a single-barrelled or double-barrelled outer sleeve, and by the methods previously described in the pending U.S. Patent Application Serial No. 08/396,414 from which the present methods differ only in the shape of the drill end or bone milling device which is essentially conical. As also previously described, in co-pending application Serial No. 08/396,414, the methods can be utilized for the insertion of non-threaded implants in which case said implants are linearly advanced rather than threaded in. And finally, as previously described in co-pending application 08/390,131, the implants themselves may have truncations on the sides to form a planar surface parallel to the longitudinal axis of the implant, such that it is possible to fit two such implants more closely together by narrowing the width of each while preserving their height.

Referring again to Figure 12, in an alternative method of implant insertion, the use of at least partially frusto-conical interbody spinal fusion implants allows for the creation of lordosis by the implant itself where none is present to begin with as with the angular relationship of V_2 and V_3 shown in Figure 12. As per this example, the disc space D_2 which in the preferred circumstance would be fully distracted but need not be, but lacking lordosis, could have a bore drilled across that space such that equal arcs of bone A_1 and A_2 are removed from each of the adjacent vertebrae V_2 and V_3 using a drill 520 or bone milling device capable of producing a cylindrical bore. Where one such boring is performed, it would generally be in the center line and directed from anterior to posterior. This might be appropriate for use in the cervical spine. More commonly and as generally would be the rule in the lumbar spine, a pair of bores would be so created from anterior to posterior, one to each side of the midline. The essential feature here is that the vertebrae, whether distracted from each other or not, are essentially lacking the full restoration of lordosis. The use of the substantially cylindrical bone removal instrument 520, (e.g. a drill), provides for the removal of a generally uniform thickness of bone from each of the

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adjacent vertebrae from anterior to posterior. The insertion of a frusto-conical implant, having a larger diameter at its trailing edge than at its leading edge, then forces the anterior aspects of the adjacent vertebrae apart more so than the posterior aspects where the diameter is lesser. This utilizes the implant to produce the desired lordosis.

insert

While the present invention has been described in detail with regards to the preferred embodiments, it is appreciated that other variations of the present invention may be devised which do not depart from the inventive concept of the present invention. In particular, it is appreciated that the various teachings described in regards to the specific embodiments herein may be combined in a variety of ways such that the features are not limited to the specific embodiments described above.

Each of the features disclosed in the various embodiments and their functional equivalents may be combined in any combination sufficient to achieve the purposes of the present invention as described herein.

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What is claimed is:

1. A frusto-conical interbody spinal fusion implant made of a material appropriate for human implantation, comprising:

a substantially frusto-conical body having an insertion end, a trailing end and an outer surface; and

bone engaging means for engaging said implant to adjacent vertebrae of the spine.

2. The spinal fusion implant of claim 1 in which said bone engaging means comprises an external thread.

3. The spinal fusion implant of claim 2 in which said external thread has a substantially cylindrical external configuration.

5. The spinal fusion implant of claim 1 in which said bone engaging means comprises a roughened outer surface.

6. The spinal fusion implant of claim 1 in which said bone engaging means comprises a plurality of posts spaced apart along at least a portion of the outer surface of said body.

7. The spinal fusion implant of claim 7 in which said plurality of posts have a head portion and a stem portion, said head portion having a wider diameter than said stem portion.

8. The spinal fusion implant of claim 1 in which said bone engaging means comprises a mesh material with a plurality interstices for receiving fusion promoting material.

10. The spinal fusion implant of claim 1 in which said implant has an internal chamber and an access opening for accessing said internal chamber.

11. The spinal fusion implant of claim 10 in which said internal chamber is capable of containing fusion promoting material.

12. The spinal fusion implant of claim 10 in which said implant

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comprises a wall surrounding said internal chamber.

13. The spinal fusion implant of claim 10 in which said wall has a plurality of openings passing therethrough in communication with said internal chamber.

14. The spinal fusion implant of claim 1 having a plurality of openings capable retaining fusion promoting material.

15. The spinal fusion implant of claim 1 in which said bone engaging means includes a plurality of surface roughenings for engaging said adjacent vertebrae and for maintaining said implant in place, said surface roughenings being present on at least a portion of the outer surface of said implant.

16. The spinal fusion implant of claim 15 in which said surface roughenings include a plurality of ratchetings.

18. The spinal fusion implant of claim 15 in which said surface roughenings include knurling.

19. The spinal fusion implant of claim 1 in which said implant comprises a bone ingrowth material.

19a. The spinal fusion implant of claim 1 in which said implant comprises a fusion promoting material

20. The spinal fusion implant of claim 10 in which said implant has a removable closing means for closing said access opening.

21. The spinal fusion implant of claim 1 in which one end of said implant includes an engagement means for engaging instrumentation for the insertion of said implant.

22. The spinal fusion implant of claim 1 in which at least a portion of said outer surface comprises wells having partial walls.

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23. [REDACTED] A partially conical spinal fusion implant made of a material appropriate for human implantation, said spinal fusion implant comprising a frusto-conical body having a maximum diameter portion; said body having an exterior surface configured to be placed in close proximity to a second partially conical spinal fusion implant, said first and second implants when placed together having a combined overall width that is less that the sum of the individual maximum diameters of each of said first and second implants.

24. The spinal fusion implant of claim 23 having a longitudinal central axis and at least one truncated side forming a planar surface parallel to said central axis.

25. The spinal fusion implant of claim 24 in which said truncated side is located at least in part at said maximum diameter portion.

26. A method for inserting at least one frusto-conical spinal fusion implant made of a material appropriate for human implantation, said implant comprising a partially conical body and bone engaging means for engaging the adjacent vertebrae in a segment of the spinal column, comprising the steps of:

distracting the two vertebrae adjacent the diseased disc and placing the two vertebrae in the desired amount of lordosis;

drilling a recipient bore across the disc space and into the adjacent vertebrae, said bore being greater in diameter than the disc space height such that some bone is removed from each of the adjacent vertebrae; and

inserting a frusto-conical spinal fusion implant into said recipient bore.

27. The method of claim 26 in which said bore is generally conical in shape.

28. The method claim 27 in which said bore is greatest in diameter

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anteriorly and tapering to a lesser diameter posteriorly.

4. The spinal fusion implant of claim 2 in which said external thread has a partially conical configuration that parallels the configuration of said body.

9. The spinal fusion implant of claim 8 in which said mesh material is made of a surgically implantable metal.

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ABSTRACT

The present invention is directed to a variety of interbody spinal fusion implants having at least a partially frusto-conical configuration and the instrumentation and methods by which the implants of the present invention can be utilized to achieve a desired anatomical lordosis of the spine. The spinal fusion implants of the present invention may be relatively solid or hollow and may have surface roughenings to promote bone ingrowth and stability. The spinal fusion implants of the present invention may have wells extending into the material of the implant from the surface for the purpose of holding fusion promoting materials and to provide for areas of bone ingrowth fixation. A variety of surface irregularities may be employed to increase implant stability and implant surface area, and/or for the purpose of advancing the spinal fusion implant into the fusion site.

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FROM: Amedeo Ferraro, Esq.

RE: Conical Spinal Fusion Implants
Our File No. P-12509

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APPLICATION FOR LETTERS PATENT

BY

GARY KARLIN MICHELSON, M.D.

FOR

FRUSTO-CONICAL INTERBODY

SPINAL FUSION IMPLANTS AND METHOD

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1.10 on the date indicated above and is addressed to:

PATENT APPLICATION
Assistant Commissioner for Patents
Washington, D.C. 20231.

Typed or
Printed Name: Sandra Mireles

Date: [REDACTED]

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BACKGROUND OF THE INVENTION

Related Applications

This application is a continuation in part of copending United States application Serial No. 08/396,414 filed on February 27, 1995 which is a continuation-in-part of United States application Serial No. 08/074,781 filed on June 10, 1993, which is a continuation in part of United States application Serial No. 07/698,674 filed on May 10, 1991 which is a divisional of application Serial No. 07/205,935 filed on June 13, 1988, now United States Patent No. 5,015,247 all of which are incorporated herein by reference.

This application is also a continuation-in-part of United States application Serial No. 08/390,131 entitled Interbody Spinal Fusion Implants filed on February 17, 1995.

Field of the Invention

The present invention relates generally to interbody spinal fusion implants, and in particular to spinal fusion implants configured to restore and maintain two adjacent vertebrae of the spine in anatomical lordosis.

Description of The Related Art

Interbody spinal fusion refers to the method of achieving bony bridging between adjacent vertebrae through the disc space, the space between adjacent vertebrae normally occupied by a spinal disc. Numerous implants to facilitate such a fusion have been described by Cloward, Brantigan, Michelson, and others, and are known to those skilled in the art. Generally, cylindrical implants offer the advantage of conforming to an easily prepared recipient bore spanning the disc space and penetrating into each of the adjacent vertebrae. Such a bore may be created by use of a drill. It is an anatomical fact that both the cervical spine and the

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lumbar spine are normally lordotic, that is convex forward. Such alignment is important to the proper functioning of the spine. Commonly, those conditions which require treatment by spinal fusion are associated with a loss of lordosis.

Michelson in U.S. Patent Application Serial No. 08/396,414, entitled APPARATUS AND METHOD OF INSERTING SPINAL IMPLANTS teaches a method for restoring the anatomical lordosis of the spine while performing the interbody fusion procedure. [REDACTED].

Therefore, there exists a need for spinal fusion implants and instrumentation that permits for the uniform depth of bone removal from each of the adjacent vertebrae while restoring anatomical lordosis.

SUMMARY OF THE INVENTION

The present invention is directed to a variety of interbody spinal fusion implants having at least a partially frusto-conical configuration and the instrumentation and methods by which the implants of the present invention can be utilized to achieve a desired anatomical lordosis of the spine.

In the preferred embodiment, the spinal fusion implants of the present invention have a body that is partially or fully frusto-conical in shape with an insertion end and a trailing end. The spinal fusion implants of the present invention may be further modified so that while the upper and lower surfaces are portions of a cone, at least one side portion may be truncated to form a planar surface that is parallel to the longitudinal axis of the implant to form straight walls. These implants may have a more tapered aspect at the small end of the cone to facilitate insertion. The spinal fusion implants of the present invention may be relatively solid or hollow and may have surface roughenings to promote bone ingrowth and stability. The spinal fusion implants of the present invention

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may have wells extending into the material of the implant from the surface for the purpose of holding fusion promoting materials and to provide for areas of bone ingrowth fixation. These wells, or holes may pass, either into or through the implant. The spinal fusion implants of the present invention may have at least one chamber which may be in communication through at least one opening to the surface of the implant and may have at least one access opening for loading the chamber with fusion promoting substances. The access opening may be capable of being closed with a cap or similar means. Still further, a variety of surface irregularities may be employed to increase implant stability and implant surface area, and/or for the purpose of advancing the spinal fusion implant into the fusion site. The exterior of the spinal fusion implant of the present invention may have wholly or in part, a rough finish, knurling, forward facing ratchetings, threads or other surface irregularities sufficient to achieve the purpose described. The spinal fusion implants of the present invention may be made of a mesh-like material, porous material, or any metal, plastic, ceramic or combination sufficient for the intended purpose. Such implants may be loaded with, composed of, or treated with materials to make them bioactive to the fusion process, and may be wholly or in part bioabsorbable.

The spinal fusion implants of the present invention offer significant advantages over the prior art implants:

1. Because the spinal fusion implants of the present invention are at least partially frusto-conical in shape and taper from the leading edge to the trailing edge, they are easy to introduce and easy to fully insert into the spinal segment to be fused.

2. As the spinal fusion implants of the present invention

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are generally implanted from the anterior to posterior aspect of the spine, the shape of the implants are consistent with the shape of the disc, which the implants at least in part replace. That is the front of the disc is normally taller than the back of the disc, which allows for normal lordosis. The implants of the present invention are similarly taller anteriorly than they are posteriorly.

3. The spinal fusion implants of the present invention allow for a minimal and uniform removal of bone from the vertebrae adjacent the disc space while still providing for an interbody fusion in lordosis when properly inserted.

4. The spinal fusion implants of the present invention conform to a geometric shape, which shape is readily producible at the site of fusion, to receive said spinal fusion implants.

The spinal fusion implants of the present invention can be made of any material appropriate for human implantation and having the mechanical properties sufficient to be utilized for the intended purpose of spinal fusion, including various metals such as cobalt chrome, stainless steel or titanium including its alloys, various plastics including those which are bio-absorbable, and various ceramics. Further, the spinal fusion implants of the present invention may comprise, wholly or in part, materials capable of directly participating in the spinal fusion process, or be coated with chemical substances such as bone, morphogenic proteins, hydroxyapatite in any of its forms, and osteogenic proteins, for the purpose of stimulating spinal fusion. The implants of the present invention may be wholly or in part bioabsorbable.

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OBJECTS OF THE PRESENT INVENTION

It is an object of the present invention to provide a spinal implant that is easily inserted into the spine, having a tapered leading end;

It is another object of the present invention to provide a spinal implant that tapers in height from one end to the other consistent with the taper of a normal spinal disc;

It is yet another object of the present invention to provide a spinal implant that is capable of maintaining anatomic alignment and lordosis of two adjacent vertebrae during the spinal fusion process;

It is still another object of the present invention to provide a spinal implant that is self stabilizing within the spine;

It is yet another object of the present invention to provide a spinal implant that is capable of providing stability between adjacent vertebrae when inserted;

It is still another object of the present invention to provide a spinal implant that is capable of participating in the fusion process by containing, being composed of, or being treated with fusion promoting substances;

It is further another object of the present invention to provide a spinal implant that is capable of spacing apart and supporting adjacent vertebrae during the spinal fusion process;

It is still further another object of the present invention to provide a spinal implant that is consistent in use with the preservation of a uniform thickness of the subchondral vertebral bone; and

It is another object of the present invention to provide a spinal implant the shape of which conforms to an easily produced complementary bore at the fusion site.

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These and other objects of the present invention will become apparent from a review of the accompanying drawings and the detailed description of the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a side elevational view of the spinal fusion implant of the present invention having a body that is frusto-conical with an external thread having a substantially uniform radius.

Figure 1A is an enlarged fragmentary view along line 1A of Figure 1 illustrating the surface configuration of the implant of Figure 1.

Figure 2 is a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention having a body and an external thread that are both frusto-conical.

Figure 2A is an alternative embodiment of the spinal fusion implant of the present invention shown with an external thread radius and thread height that are not constant.

Figure 3 is as cross sectional view along line 3--3 of the implant of Figure 2.

Figure 4 is a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention having a frusto-conical body and a surface configuration comprising ratchetings for engaging bone, with surface blasting, wells, and channels for bone ingrowth.

Figure 4A is a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention having truncated sides and ratchetings having a radius and height that are not constant.

Figure 4B is a top plan view of the spinal fusion implant shown in Figure 4A.

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Figure 5 is a cross sectional view along line 5--5 of the implant of Figure 4 illustrating the channels and wells of the implant of the present invention.

Figure 6 is a cross sectional view along line 6--6 of the implant of Figure 4 illustrating the channels and walls of the implant of the present invention.

Figure 7 is a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention having a body that is made out of a fibrous metal mesh that is partially frusto-conical with one side that is truncated shown next to an identical second implant illustrated in hidden line.

Figure 8 is sectional view along line 8--8 of the implants of Figure 7.

Figure 9A is an enlarged fragmentary view along line 9 of Figure 7 illustrating the surface configuration of the implant of Figure 7.

Figure 9B is an enlarged fragmentary view along line 9 of Figure 7 illustrating the surface configuration of the implant of the present invention made of a cancellous material.

Figure 10 is a side elevational view in partial cut-away of an alternative embodiment of the spinal fusion implant of the present invention having a body that is frusto-conical and a surface configuration comprising a plurality of spaced apart posts.

Figure 11 is an enlarged fragmentary sectional view along lines 11--11 of Figure 10 illustrating the surface configuration of the implant of Figure 11.

Figure 12 is a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention.

Figure 13 is a side elevational view of a segment of the spinal column in lordosis having the spinal fusion implant of Figure 12 being implanted with a driving instrument from the posterior approach.

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Figure 14 is a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention.

Figure 15 is an end view along line 15--15 of the spinal fusion implant of Figure 14 shown placed beside a second identical implant shown in hidden line.

Figure 16 is a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention.

Figure 17 is a side elevational view of a segment of the spinal column partially in lordosis showing a first drill and a second drill used in the method of the present invention.

DETAILED DESCRIPTION OF THE DRAWINGS

Referring to Figure 1, a side elevational view of the spinal fusion implant of the present invention generally referred to by numeral 20 is shown. The implant 20 has a body 22 that is frusto-conical in shape such that the body 22 has a diameter (root diameter) that is frusto-conical in shape. The body 22 has an insertion end 24 and a trailing end 26. In the preferred embodiment, the body 22 of the implant 20 has a maximum diameter at a point nearest to the trailing end 26 and a minimum diameter at a point nearest to the insertion end 24.

The implant 20 has an external thread 28 having a substantially uniform radius R_1 measured from the central longitudinal axis L_1 of the implant 20, such that the external diameter of the external thread 28 (major diameter) has an overall configuration that is substantially parallel to the longitudinal axis L_1. While the major diameter of the implant 20 is substantially uniform, the external thread 28 may be modified at the leading edge by having initially a reduced thread radius to facilitate insertion of the implant 20 and may also be modified to make the external thread 28 self-tapping. In the preferred embodiment, the external thread 28 has a first thread 30 of a

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lesser radius than the radius R_1 of the remainder of the external thread 28 to facilitate insertion of the implant 20. The second thread 32 has a greater radius than the first thread 30, but is still shorter than the radius R_1 of the remainder of the external thread 28 which is thereafter of constant radius.

The frusto-conical configuration of the body 22 allows for the creating and maintaining of the adjacent vertebrae of the spine in the appropriate angular relationship to each other in order to preserve and/or restore the normal anatomic lordosis of the spine. The substantially uniform radius R_1 of the external thread 28 of the implant 20 allows for the engaging of the bone of the adjacent vertebrae in a position that counters the forces which tend to urge the implant 20 from between the adjacent vertebrae in the direction opposite to which the implant 20 was implanted. Also, the configuration of the external thread 28 increases the surface area of the implant 20 in contact with the bone promoting bone ingrowth.

The implant 20 has a recessed slot 34 at its trailing end 26 for receiving and engaging insertion instrumentation for inserting the implant 20. The recessed slot 34 has a threaded opening 36 for threadably attaching the implant 20 to the insertion instrumentation.

Referring to Figure 1A, the implant 20 has an outer surface 38 that is porous to present an irregular surface to the bone to promote bone ingrowth. The outer surface 38 is also able to hold fusion promoting materials and provides for an increased surface area to engage the bone in the fusion process and to provide further stability. It is appreciated that the outer surface 38 and/or the entire implant 20 may comprise of any other porous material or roughened surface sufficient to hold fusion promoting substances and/or engage the bone during the fusion process. The implant 20 may be further coated with bioactive

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fusion promoting substances including, but not limited to, hydroxyapatite compounds, osteogenic proteins and bone morphogenic proteins. The implant 20 is shown as being solid, however it is appreciated that it can be made to be entirely hollow or hollow in part.

In the preferred embodiment, for use in the lumbar spine, the implant 20 has an overall length in the range of approximately 27 mm to 30 mm with 26 mm being the preferred length. The body 22 of the implant 20 has a root diameter at the insertion end 24 in the range of 10-20 mm, with 16 mm being the preferred root diameter at the insertion end, and a root diameter at the trailing end 26 in the range of 12-24 mm, with 19 mm being the preferred diameter at the trailing end 26. In the preferred embodiment, the implant 20 has a thread radius R_1 in the range of 8 mm to 12 mm, with 10 mm being the preferred radius R_1. For use in the cervical spine, the implant 20 has an overall length in the range of approximately 10-22 mm, with 12-14 mm being the preferred length. The body 22 of the implant 20 has a root diameter at the insertion end 24 in the range of _____ mm, with __ mm being the preferred root diameter at the insertion end, and a root diameter at the trailing end 26 in the range of ____ mm, with __ mm being the preferred root diameter at the trailing end 26; a thread radius R_1 in the range of approximately 4-12 mm, with 5-6 mm being the preferred radius R_1 when inserted side by side in pairs, and 7-10 mm when inserted singularly.

Referring to Figure 2, an alternative embodiment of the spinal fusion implant of the present invention is shown and generally referred to by the numeral 120. The implant 120 has a body 122 that is frusto-conical in shape similar to body 20 of implant 20, and has an insertion end 124 and a trailing end 126. The implant 120 has an external thread 128 having a radius R_2 measured from the central longitudinal axis L_2 that is not

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constant, a thread height that is constant with respect to the body 122 and which parallels the body 122 such that the external thread 128 is also frusto-conical in shape. The implant 120 has an outer surface with large openings 140 and small openings 142 permitting bone ingrowth into the implant 120.

Referring to Figure 2A, an alternative embodiment of implant 120 is shown and generally referred to by the numeral 120'. The implant 120' has an external thread 128' having a radius R_3 measured from the central longitudinal axis L_3 of the implant 120'. The thread radius R_3 is not constant throughout the length of the implant 120' and the external thread 128' has a thread height that is also not constant with respect to the body 122' of the implant 120'. In the preferred embodiment, the implant 120' has an external thread 128' with a radius R_3 that increases in size from the insertion end 124' to the trailing end 126' of the implant 120'.

Referring to Figure 3, a cross sectional view along line 3--3 of the implant 120 is shown. The implant 120 has an outer wall 144 surrounding an internal chamber 146. The large and small openings 140 and 142 may pass through the outer wall 144 to communicate with the internal chamber 146. The internal chamber 146 may be filled with bone material or any natural or artificial bone growth material or fusion promoting material such that bone growth occurs from the vertebrae through the openings 140 and 142 to the material within internal chamber 146. While the openings 140 and 142 have been shown in the drawings as being circular, it is appreciated that the openings 140 and 142 may have any shape, size configuration or distribution, suitable for use in a spinal fusion implant without departing from the scope of the present invention.

The implant 120 has a cap 148 with a thread 150 that threadably attaches to one end of the spinal fusion implant 120.

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The cap 148 is removable to provide access to the internal chamber 146, such that the internal chamber 146 can be filled and hold any natural or artificial osteoconductive, osteoinductive, osteogenic, or other fusion enhancing material. Some examples of such materials are bone harvested from the patient, or bone growth inducing material such as, but not limited to, hydroxyapatite, hydroxyapatite tricalcium phosphate; or bone morphogenic protein. The cap 148 and/or the spinal fusion implant 120 may be made of but not limited to any material appropriate for human implantation including metals such as cobalt chrome, stainless steel, titanium, plastics, ceramics, composites and/or may be made of, and/or filled, and/or coated with a bone ingrowth inducing material such as, but not limited to, hydroxyapatite or hydroxyapatite tricalcium phosphate or any other osteoconductive, osteoinductive, osteogenic, or other fusion enhancing material. The cap 148 and the implant 120 may be partially or wholly bioabsorbable.

Referring to Figure 4, an alternative embodiment of the spinal fusion implant of the present invention is shown and generally referred to by the numeral 220. The implant 220 has a frusto-conical body 222 and has a surface configuration of forward facing ratchetings 240 suitable for engaging the bone of the adjacent vertebrae. Each of the plurality of ratchetings 240 has a bone engaging edge 242 and ramped portion 244.

The orientation of the ratchetings 240 makes the insertion of the implant 220 easier than its removal, as the ramped portions 244 act as an inclined plane on the way in, while the bone engaging edges 242 resist motion in the opposite directions. These forward facing ratchetings 240 tend to urge the implant 220 forward until the unremoved bone of the vertebrae blocks further motion resulting in a very stable spine and implant construct.

In the preferred embodiment, the bone engaging edges 242 of the ratchetings 240 have a height at a highest point measured

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from the root diameter of the implant 220 in the range of 0.25 - 2.0 mm, with the preferred height being 0.4 mm for use in the cervical spine and 1.25 mm for use in the lumbar spine.

Referring to Figures 5 and 6, cross sectional views of implant 220 are shown. The implant 220 has channels 250 passing through the implant 220 and wells 260 formed in the surface of the implant 220. The wells 260 may or may not communicate with the channels 250. In the preferred embodiment of implant 220, the channels 250 have a diameter in the range of 0.1 mm to 6 mm, with 2-3 mm being the preferred diameter. The wells 260 have a diameter in the range of 0.1 mm to 6 mm, with 1-3 mm being the preferred diameter range. It is appreciated that although the channels 250 and wells 260 are shown having a generally rounded configuration, it is within the scope of the present invention that the channels 250 and wells 260 may have any size, shape, configuration, and distribution suitable for the intended purpose.

Referring to Figures 4A and 4B, an alternative embodiment of the implant 220 is shown and generally referred to by the numeral 220'. The implant 220' has ratchetings 240' having a radius R_4 measured from the longitudinal central axis L_4 that increases in size from the insertion end 224' to the trailing end to the trailing end 226'. The ratchetings 240' each have a height measured from the body 222' that is not constant throughout the length of the implant 220'. In the preferred embodiment, the thread radius R_4 and the thread height increase in size from the insertion end 224' to the trailing end 226'.

As shown in Figure 4B, the implant 220' has truncated sides 270 and 272 forming two planar surfaces which are diametrically opposite and are parallel to the longitudinal axis L_4. In this manner, two implants 220' may be placed side by side with one of the sides 270 or 272 of each implant touching, such that the area of contact with the bone of the adjacent vertebrae

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and the ratchetings 240' is maximized.

Referring to Figures 7-9A, an alternative embodiment of the spinal fusion implant of the present invention is shown and generally referred to by the numeral 320a. The implant 320a is shown placed next to a second implant 320b shown in hidden line. The implant 320a has a body 322 that is made out of a mesh-like material comprising strands which may be made of metal that are pressed together and molded into a partially frusto-conical configuration. The implant 320a has an insertion end 324 and a trailing end 326 and may be made entirely of a mesh-like material or may comprise an outer covering made of the mesh-like material. It is appreciated that the implant 320a may be solid or may be partially hollow and include at least one internal chamber.

As shown in Figure 9A, the mesh-like material comprises strands that are formed and pressed together such that interstices 339, capable of retaining fusion promoting material and for allowing for bone ingrowth, are present between the strands in at least the outer surface 338 of implant 320.

Referring to Figure 9B, alternatively the implant 320a may be made of a cancellous material 350 such that the outer surface 338 has a configuration as shown in Figure 9B. As the implant 320a may be made entirely or in part of the cancellous material 350, the interstices 352 may be present in the outer surface 338 and/or within the entire implant 320a to promote bone ingrowth and hold bone fusion promoting materials.

Referring again to Figure 8, the implant 320a is partially frusto-conical, similar in shape to implant 20 but having at least one truncated side 340 that forms a planar surface parallel to the longitudinal axis of implant 320. The truncated side 340 allows for the placement of two implants 320a and 320b closer together when placed side by side between two adjacent vertebrae as set forth in U.S. Patent Application Serial No.

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08/390,131, incorporated herein by reference [REDACTED].

Referring to Figure 10, a side elevational view in partial cut-away of an alternative embodiment of the implant of the present invention is shown and generally referred to by the numeral 420. The implant 420 has a body 422 that is frusto-conical in shape having an insertion end 424 and a trailing end 426. The implant 420 has an outer surface 438 that is capable of receiving and holding bone, or other materials capable of participating in the fusion process and/or capable of promoting bone ingrowth. In the preferred embodiment, the surface 438 comprises a plurality of posts 440 that are spaced apart to provide a plurality of interstices 442 which are partial wells with incomplete walls capable of holding and retaining milled bone material or any artificial bone ingrowth promoting material. The implant 420 may be prepared for implantation by grouting or otherwise coating the surface 438 with the appropriate fusion promoting substances.

Referring to Figure 11, an enlarged view of the surface 438 of implant 420 is shown. In the preferred embodiment, the posts 440 have a head portion 444 of a larger diameter than the remainder of the posts 440, and the each of the interstices 442 is the reverse configuration of the posts 444 having a bottom 446 that is wider than the entrance 448 to the interstices 442. Such a configuration of the posts 440 and interstices 442 aids in the retention of bone material in the surface 438 of the implant 420 and further assists in the locking of the implant 420 into the bone fusion mass created from the bone ingrowth, while providing for an improvement in the available amount of surface area which may be still further increased by rough finishing, flocking or otherwise producing a non smooth surface.

In the preferred embodiment, the posts 440 have a maximum diameter in the range of approximately 0.1-2 mm and a height of approximately 0.1-2 mm and are spaced apart a distance of

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approximately 0.1-2 mm such that the interstices 442 have a width in the range of approximately 0.1 to 2mm. The post sizes, shapes, and distributions may be varied within the same implant.

Referring to Figure 13, a side elevational view of an alternative embodiment of the spinal fusion implant of the present invention generally referred to by numeral 520 is shown. The implant 520 has a body 522 having a root diameter that is frusto-conical in the reverse direction as that of implant 20 in order to preserve and/or restore lordosis in a segment of spinal column when inserted from the posterior aspect of the spine. The body 522 has an insertion end 524 and a trailing end 526. In the preferred embodiment, the body 522 of the implant 520 has a minimum diameter at a point nearest to the trailing end 526 and a maximum diameter at a point nearest to the insertion end 524.

The implant 520 has an external thread 528 having a substantially uniform radius R_5 measured from the central longitudinal axis L_5 of the implant 520, such that the external diameter of the external thread 528 (major diameter) has an overall configuration that is substantially parallel to the longitudinal axis L_5. It is appreciated that the thread 528 can have a major diameter that varies with respect to the longitudinal axis L_5, such that the major diameter may increase from the insertion end 524 to the trailing end 526.

Referring to Figure 14, a segment of the spinal column S is shown with the vertebrae V_1 and V_2 in lordosis and an implant 520 shown being inserted from the posterior aspect of the spinal column S with an instrument driver D. The implant 520 is inserted with the larger diameter insertion end 524 first in order to in initially distract apart the vertebrae V_1 and V_2 which then angle toward each other as the implant 520 is fully inserted. It is appreciated that the insertion of implant 520 does not require the adjacent vertebrae V_1 and V_2 to be placed in lordosis prior to

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insertion, as the full insertion of the implant 520 itself is capable of creating the desired lordotic angular relationship of the two vertebrae V_1 and V_2.

In the preferred embodiment, for use in the lumbar spine, the implant 520 has an overall length in the range of approximately 27 mm to 30 mm with 26 mm being the preferred length. The body 522 of the implant 520 has a root diameter at the insertion end 524 in the range of 12-24 mm, with 14.5 mm being the preferred root diameter at the insertion end, and a root diameter at the trailing end 526 in the range of 10-20 mm, with 12.5 mm being the preferred diameter at the trailing end 526. In the preferred embodiment, the implant 520 has a thread radius R_5 in the range of 6 mm to 12 mm, with 8 mm being the preferred radius R_5.

Referring to Figure 15, an alternative embodiment of the spinal fusion implant of the present invention generally referred to by the numeral 620 with a partial fragmentary view of a second identical implant generally referred to by the numeral 621 are shown. The implant 620 has a body 622 that is partially frusto-conical in shape similar to body 222' of implant 220' shown in Figure 4A, and has an insertion end 624 and a trailing end 626. The body 622 of the implant 620 has truncated sides 670 and 672 forming planar surfaces that are parallel to the longitudinal axis L_6. In this manner, two implants 620 and 621 may be placed side by side, with one of the sides 670 or 672 of each implant touching, such that the area of contact with the bone of the adjacent vertebrae is maximized. It is appreciated that the body 622 may also be cylindrical in shape and have truncated sides 670 and 672.

The implant 620 has an external thread 628 having a radius R_6 measured from the central longitudinal axis L_6 that may be constant such that the major diameter of the external thread 628 has an overall configuration that is substantially cylindrical. It is appreciated that the external thread 628 may have a thread

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